

# Exhibit B

## EXECUTIVE SUMMARY<sup>1</sup>

### PRELIMINARY RECOMMENDATIONS ON TESTING METHODS FOR ASBESTOS IN TALC AND CONSUMER PRODUCTS CONTAINING TALC

January 6, 2020

In the fall of 2018, the United States Food and Drug Administration (US FDA) formed the Interagency Working Group on Asbestos in Consumer Products (IWGACP), with representatives from eight federal agencies<sup>2</sup>, to support the development of standardized testing methods for asbestos and other mineral particles of health concern in talc that could potentially affect consumer product safety.<sup>3</sup> The IWGACP was formed in response to reports of the presence of asbestos in talc-containing cosmetic products, with talc being the presumptive source of asbestos. Since 2017, there have been several [voluntary recalls of cosmetic products](#) by retailers in the US and globally ([Canada](#), [Netherlands](#), [Taiwan](#)) due to the presence of asbestos.

Talc is a hydrated magnesium silicate mineral that is used in a wide variety of consumer products including cosmetics, foods, dietary supplements, drugs, medical devices, ceramics, and art materials. Raw material talc is obtained from mines that may also contain asbestos and related minerals. Removal of asbestos by purification of talc ores is extremely difficult. Thus, judicious selection of talc deposits and mining locations within the deposits is necessary to avoid contamination with asbestos and similar biologically active mineral particles. It is imperative that appropriate monitoring methods are available to detect asbestos in talc to ensure its suitability as a raw material for use as an ingredient in consumer products.

The health hazards associated with asbestos are well documented. There is general agreement among US federal agencies, most developed nations, and the World Health Organization (WHO) that there is no known safe level of asbestos exposure. Inhalation of asbestos, from any source, is a safety concern because it can cause the formation of scar-like tissue in the lung, resulting in

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<sup>1</sup> The recommendations and opinions expressed in this document are based on discussions on matters of “scientific debate” (contentious issues that have not been completely resolved or finalized in the ongoing debate) among subject matter experts on the IWGACP and do not necessarily reflect the opinions or policies of their agencies. These recommendations do not represent proposed changes to any regulations of the U.S. Government. The use of the terms “IWGACP” or “we” refers to the consensus opinion of the working group scientists and not the individual experts or the agencies they represent.

<sup>2</sup> Food and Drug Administration (FDA), National Institutes for Occupational Safety and Health (NIOSH), National Institute of Health (NIH)/ National Institute of Environmental Health Sciences (NIEHS), Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC), the National Institute of Standards & Technology (NIST), and the Department of Interior’s U.S. Geological Survey (USGS). The participating federal agencies have expertise in asbestos-testing and/or asbestos-related issues (e.g., from a health perspective), or because they regulate some of the consumer products that contain talc as an ingredient.

<sup>3</sup> By “consumer products”, we are referring to products used by consumers, which are regulated by a variety of federal agencies. This includes, but is not limited to, “consumer products” as defined under the Consumer Product Safety Act.

asbestosis or pleural plaques, or it may lead to the development of lung cancers and mesothelioma. Exposure to asbestos may also lead to the development of other cancers.<sup>4</sup>

Concern about the purity of talc used as a raw material was heightened in the early 1970s when numerous cosmetic products tested positive for asbestos. However, at that time the development of asbestos testing methods was still in its infancy. In 1976, the cosmetics industry implemented voluntary asbestos testing of talc raw materials using the Cosmetic, Toiletry, and Fragrance Association (CTFA) J4-1 method. Talc suppliers to the pharmaceutical industry use a similar method to certify that talc meets the United States Pharmacopeia's (USP's) requirement for "Absence of Asbestos." To date, both methods rely on the use of X-ray diffraction (XRD) or infrared (IR) spectroscopy followed by polarized light microscopy (PLM) only if XRD or IR is positive for amphibole or serpentine minerals in talc. The CTFA J4-1 and USP methods remain standard test methods despite long-recognized shortcomings in specificity and sensitivity compared with electron microscopy-based methods.

In 2010, FDA asked the USP to consider revising the current tests for asbestos in talc to ensure adequate specificity, and in 2014 the Talc USP expert panel recommended an update of the Talc USP monograph to require an electron microscopy method for the measurement of asbestos in talc (Woodcock, 2010<sup>5</sup>; Block et al. 2014<sup>6</sup>). Recent reports from testing of cosmetic products indicate that because of shortcomings in sensitivity, light microscopy (polarized light microscopy; PLM) sometimes fails to detect finely-sized particles of asbestos and similar minerals even when they are present in talc. Moreover, modern laboratories with expertise in asbestos testing, when asked to test talc-containing consumer products, routinely perform electron microscopy and do not rely solely on PLM. These findings provide support to recommendations from many scientific experts, including those on this Working Group, that transmission electron microscopy (TEM) should be used for asbestos-testing of talc, even if the findings of PLM are negative. (See, for example, Rohl and Langer, 1974<sup>7</sup>, Millette 2015<sup>8</sup>, Block et al. 2014<sup>5</sup>).

There are many definitions of "asbestos" used in the commercial, geological, and legal domains. As a commercial term, asbestos refers to a group of six mined minerals that have commercially useful properties including flexibility, durability, and heat-resistance. Mineralogists define "asbestos" as those silicate minerals belonging to the serpentine and amphibole groups which have an unusual fibrous (asbestiform) crystal growth habit as opposed to non-asbestiform crystal

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<sup>4</sup> *Asbestos: Selected Cancers*, 2006, Institute of Medicine of the National Academy, Committee on Asbestos; International Agency for Research on Cancer (IARC), 2012, IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans. Monograph 100C. A Review of Human Carcinogens: Arsenic, Metals, Fibres, and Dusts.

<sup>5</sup> Woodcock, J. (2010) Letter to Roger L. Williams, CEO of USP (October 12, 2010). See <https://www.usp.org/sites/default/files/usp/document/get-involved/monograph-modernization/2010-10-12-letter-from-dr-janet-woodcock.pdf>

<sup>6</sup> Block LH, Beckers D, Ferret J, Meeker GP, Miller A, Osterberg RE, Patil DM, Pier JW, Riseman S, Rutstein MS, Tomaino GP, Van Orden DR, Webber JS, Medwid J, Wolfgang S, and Moore K (2014) Stimuli to the Revision Process, Modernization of Asbestos Testing in USP Talc USP-PF 40(4) <https://www.fairwarning.org/wp-content/uploads/2017/12/11TalcDoc.pdf>

<sup>7</sup> Rohl AN and Langer AM. (1974) Identification and quantitation of asbestos in talc. *Environ Health Perspect.* 9: 95-109.

<sup>8</sup> Millette JR (2015) Procedure for the Analysis of Talc for Asbestos. *The Microscope* 63(1): 11-20.

growth. US asbestos regulations and the test methods required to establish regulatory compliance specify each regulated type of asbestos using mineral and commercial nomenclature. Most US regulations specify the six asbestos minerals historically used commercially: chrysotile (a member of the serpentine group) and asbestiform riebeckite (commercially called “crocidolite”), asbestiform grunerite-cummingtonite (commercially called “amosite”), tremolite asbestos, anthophyllite asbestos, and actinolite asbestos (with the latter five being members of the amphibole group).

Asbestos regulations and standard methods for analysis contain a wide variety of “counting rules” designating how to quantify asbestos in occupational or environmental settings using various microscopic methods. Rules were tailored to simplify counting, to improve statistical analysis, and to provide a threshold for mitigating risk when asbestos is known to be present. To date, counting rules have not specifically considered biological activity, overt toxicity, or epidemiology of the kinds of chrysotile and amphibole particles being detected and counted. That is, all mineral particles meeting specified criteria for mineral type and dimensions are expected to be reported and counted.

Importantly, testing methods pertaining to asbestos in articles of commerce were developed for analyzing “bulk materials” containing at least 1% asbestos as an intentional ingredient by weight or in settings where asbestos was known to be present (*e.g.* mines, mills, factories, schools, and other settings). Published methods for analysis of bulk materials were not intended to determine the presence of asbestos in products at less than 1% concentration. In contrast, the likely amount present when asbestos is a contaminant or impurity in talc or talc-containing consumer products might be orders of magnitude below 1%.

Because no single published testing method can be followed, as written, for the analysis of asbestos in talc and talc-containing consumer products, analytical laboratories appear to be adapting published testing methods that were intended for analysis of asbestos in air or building materials. Thus, to help reconcile potential discrepancies in reports of analysis, IWGACP recommends the development of a standardized method specifically for the analysis of asbestos and other biologically active EMPs in talc and talc-containing consumer products for use by government regulatory authorities, industry, and contracting laboratories. Rigorous training requirements, quality assurance, and quality control would need to accompany the implementation of these methods to maintain consistency of results across the field.

The difficulty of identifying and quantifying individual asbestos or other mineral particles present at low concentrations in talc is compounded by the presence of non-asbestiform analogs with the same elemental composition and crystal structure, but different growth habit. Using TEM, differentiation of chrysotile from non-asbestiform serpentine analogs is relatively straightforward; however, each of the non-asbestiform amphiboles can disaggregate into particles resembling asbestiform fibers, giving rise to disputes between laboratories over whether elongate amphibole particles are truly asbestos, or are particles resulting from attrition of larger particles of a non-asbestiform analog. Because both types of elongate minerals are suspected of having biological activity with similar pathological outcomes, the distinction is irrelevant. Lack of consensus concerning what should be called “asbestos” has persisted since the first reports indicating that asbestos might be present in talc used in cosmetics and has inhibited thorough toxicological and epidemiological investigations of disease attributable to talc that contains asbestos.

In light of this lack of consensus, the IWGACP considered applicable published asbestos test methods<sup>9</sup> and other published documents in developing recommendations for terminology, analytical techniques, and criteria for qualitative and quantitative measurement of asbestos in talc and talc-containing consumer products. Based on its review, the IWGACP agrees with the recommendations and rationale provided in the peer reviewed NIOSH Bulletin 62<sup>10</sup> regarding adopting the term “elongate mineral particle” or “EMP” that is defined as “*any mineral particle with a minimum aspect ratio [i.e., length: width ratio] of 3:1.*” Thus, an EMP encompasses both asbestiform and non-asbestiform particles that have dimensions that enable them to be respirable. NIOSH Bulletin 62 also introduced two terms “covered mineral” and “countable EMP,” that appear to be applicable to the analysis of talc and talc-containing products. A “covered mineral” is defined as “*a mineral encompassed by a specified regulation or recommended standard*” and a “countable EMP” as “*a particle that meets specified dimensional criteria and is to be counted according to an established protocol.*” However, for talc and talc-containing products, the recommendations for covered minerals and countable EMP dimensions differ from those discussed in Bulletin 62 for the NIOSH recommended exposure limit (REL). For talc and talc-containing products:

- Covered minerals include chrysotile (but not other serpentine minerals) and members of the amphibole group (inclusive; not restricted to the five amphiboles used commercially).
- Countable EMPs have an aspect ratio (AR) of  $\geq 3:1$  and a length of  $> 0.5 \mu\text{m}$  using the most inclusive criteria for length and AR from among the “asbestos” counting rules in established testing protocols. The specified minimum length of  $0.5 \mu\text{m}$  is consistent with the counting rules for fibers established by the global standard for TEM sampling and analysis, ISO 10312:2019 (Appendix C) and is supported by studies that indicate asbestos particles and EMPs of these dimensions could pose a health concern.<sup>11</sup>

<sup>9</sup> The Cosmetic, Toiletry, and Fragrance Association (CTFA) J4-1 Method (1976): <http://www.asbestosandtalc.com/EMP%20Detection%20Limits%20ASTM/PCPC000960.pdf>; United States Pharmacopeia (USP) standard for talc (2011): [http://ftp.uspbpep.com/v29240/usp29nf24s0\\_m80360.html](http://ftp.uspbpep.com/v29240/usp29nf24s0_m80360.html); <https://www.astm.org/Standard/standards-and-publications.html>; USP Food Chemicals Codex (2019): <https://www.foodchemicalscodex.org/>; various ASTM, ISO, EPA, and NIOSH standards: <https://www.astm.org/Standard/standards-and-publications.html>; <https://www.iso.org/standards.html>; <https://www.epa.gov/asbestos/asbestos-laws-and-regulations>; [https://www.cdc.gov/niosh/pubs/all\\_date\\_desc\\_nopubnumbers.html](https://www.cdc.gov/niosh/pubs/all_date_desc_nopubnumbers.html)

<sup>10</sup> NIOSH (2011) “Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research” *Current Intelligence Bulletin* 62. Department of Health and Human Services. Centers for Disease Control and Prevention. National Institute for Occupational Safety and Health. Publication No. 2011-159 (March 2011). <http://www.cdc.gov/niosh/docs/2011-159/pdfs/2011-159.pdf>.

<sup>11</sup> For example, see Suzuki and Yuen (2002) Asbestos fibers contributing to the induction of human malignant mesothelioma. *Ann NY Acad Sci* 982: 160-176: <https://www.ncbi.nlm.nih.gov/pubmed/12562635>; Dodson et al. (2003) Asbestos fiber length as related to potential pathogenicity: a critical review. *Am J. Ind. Med.* 44: 291-297: <https://www.ncbi.nlm.nih.gov/pubmed/12929149>; Suzuki et al. (2005) Short, thin, asbestos fibers contribute to the development of human malignant mesothelioma: pathological evidence. *Int. J. Hyg. Environ. Health* 208(3): 201-210: <https://www.ncbi.nlm.nih.gov/pubmed/15971859>; Boulanger et al. (2014) Quantification of short and long asbestos fibers to assess asbestos exposure: a review of fiber size toxicity. *Environmental Health* 13:59: <https://www.ncbi.nlm.nih.gov/pubmed/25043725>; ANSES (2015) Opinion of the French Agency for Food, Environmental and Occupational Health and Safety on “Health effects and the identification of cleavage fragments of amphiboles from quarried minerals”: <https://www.anses.fr/en/system/files/AIR2014sa0196RaEN.pdf>.

The optimal analytical approach should address potential interference by sample matrices and thereby ensure sensitivity at levels or concentrations that are protective of public health. In addition, multiple sampling and analysis methods will be required to provide all the information that is needed to make health protective identification and classification of asbestos and other EMPs of potential concern. To improve agreement in data interpretation among stakeholders and resolve inconsistencies in applying published methods and counting criteria, IWGACP recommends minimum content and format for analytical reports. IWGACP also suggests written protocols that specify appropriate instruments, methods, and counting rules for the detection, quantification, and classification of EMPs. In conclusion, the IWGACP recommends:

1. Adoption of the term EMP as “*any mineral particle with a minimum aspect ratio of 3:1*”, consistent with how this term is defined in the NIOSH Bulletin 62, to resolve ambiguity and disagreement in mineral (asbestos versus non-asbestos) identification.
2. Testing laboratories report all EMPs having length  $\geq 0.5 \mu\text{m}$  (500 nm).
3. That test methods specify reportable EMPs identified as amphibole or chrysotile particles as covered minerals.
4. Test methods require the counting and reporting of covered EMPs as a function of sample mass. When counting, IWGACP recommends referring to guidelines such as ISO 10312 to classify primary and secondary structures. Individual fibers in secondary structures can be counted recording the dimensions of each fiber.
5. Use of TEM at nominally 20,000x magnification, in addition to PLM, to resolve the issues of sensitivity that cause reporting of false negatives for covered EMPs. IWGACP strongly recommends using TEM with energy dispersive X-ray spectroscopy (EDS) and selected area electron diffraction (SAED) analyses to reliably detect and identify chrysotile and asbestiform and non-asbestiform amphibole minerals, including EMPs whose narrowest width is  $<200 \text{ nm}$  (the limit of resolution for light microscopy). SEM might be useful as a complementary method but has significant shortcomings for identification of chrysotile and visualization of the narrowest particles in the population that can only be overcome by using TEM.
6. That “mass percent,” a unit that is frequently used to express content of asbestos in commercial bulk materials, is not appropriate for measurement of EMPs in talc and consumer products containing talc because weight percent does not correlate with the number of fibers, and one large fiber could dominate the mass percent value.
7. Although IWGACP concludes that criteria for differential counting and classification of EMPs meeting criteria in #2 would be beneficial, no specific recommendations were agreed upon during deliberations. Therefore, at this time the IWGACP recommends reporting and counting all EMPs of covered minerals under a single classification with additional information that would allow further classification based on measurements such as mineral type and dimensions in the future.

In addition, the IWGACP has identified the following as areas for directing efforts to promote reliability of the analytical methods for asbestos and other EMPs of health concern in talc and talc-containing consumer products:

- Validation of analytical methods (XRD, PLM, TEM) specific to talc and consumer products containing talc that minimize false positive and false negative results.
- Research and validation of methods of sampling that maximize sample representativeness and minimize error and false positives and false negatives.
- Research on methods for sample preparation, in particular, treatments (e.g. “concentration methods”) that improve sensitivity while leaving covered minerals unchanged with respect to identity and dimensions.
- Development of talc-specific reference standards with known concentrations of specific EMPs that can be used to assess laboratory and analyst proficiency, increase inter-laboratory concurrence in method validation, minimize reporting errors, and potentially provide for improved reliability of quantitative analysis.